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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/525,986

02/25/2005

Tadashi Nakajima

05116/HG

5004

1933 7590 09/14/2010

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EXAMINER

BASQUILL, SEAN M

ART UNIT

PAPER NUMBER

1613

MAIL DATE

DELIVERY MODE

09/14/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/525,986	Applicant(s) NAKAJIMA ET AL.	
	Examiner Sean Basquill	Art Unit 1613	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>29 Jun 2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Previous Rejections

Applicants' arguments, filed 29 June 2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1 and 2, and 21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over EP/0286903A1 ("Bito"), in view of U.S. Patent 7,015,210 ("Aiken"), P. Vasantha Rao, et al, *Modulation of Aqueous Humor Outflow Facility by the Rho Kinase-Specific Inhibitor Y-27632*, 42 INV. OPHTHALMOL. VIS. SCI. 1029 (April 2001) ("Rao"), U.S. Patent 6,271,224 ("Kapin") (all of record), as put forth in the previous office actions.

Applicants arguments have been fully considered and are deemed unpersuasive. As a threshold matter, applicants are reminded that obviousness necessarily take into consideration the total knowledge possessed by the skilled artisan, not merely the information conveyed by an individual reference. As such, in the context of an obviousness rejection, arguments directed to the disclosure of references individually cannot serve to overcome an obviousness rejection. MPEP § 2145(IV). Where multiple references from analogous art each teach individual

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elements of a claimed invention, and the examiner provides a rationale which the skilled artisan at the time of the invention claimed could have employed to unite the individual teachings of the relied upon references, a *prima facie* case of obviousness is established. *KSR International Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007) Such a *prima facie* case can only be overcome by amending the claims to exclude the relied upon art, or, by proper submission of objective indicia of nonobviousness commensurate in scope with the invention claimed, demonstrate some degree of unexpected results were obtained by the combination claimed. MPEP § 716, et seq. Such unexpected results must indeed be unexpected by the skilled artisan, and must be determined in comparison to the closest art which actually exists. *Id.* Here, the only objective data applicants have repeatedly provided relies on comparisons to the individual components of the combination composition in relation to a placebo control and to the individual elements of the combination composition, using only two of the four claimed prostaglandins. This evidence cannot form the basis of a determination that the claimed combination presents unexpected results, as not only have applicants failed to compare the claimed invention to the closest prior art, they have also failed to demonstrate the an unexpected improvement in the IOP lowering result of the combination, which may support a conclusion of nonobviousness. Indeed, from the data presented, it appears that the combination of a prostaglandin and rho kinase inhibitor provides less than additive reduction of intraocular pressure. As such, no objective evidence in support of nonobviousness has been made of record, and the examiner's rejection shall stand.

Conclusion

No Claims stand allowable.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean Basquill whose telephone number is (571) 270-5862. The examiner can normally be reached on Monday through Thursday, between 8AM and 6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Kwon can be reached on (571) 272-0581. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean Basquill/
Examiner, Art Unit 1613

/Jeffrey S. Lundgren/
Primary Examiner, Art Unit 1639